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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

EUGENE DIVISION

PARTNERS IN CARE, INC., an Oregon nonprofit corporation, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health & Human Services, Defendant.	Case No. **COMPLAINT** (Complaint for Judicial Review of Administrative Decision - 28 USC § 1331; 42 USC § 1395ff(b); 5 U.S.C. § 551 *et seq*.)

COMPLAINT FOR JUDICIAL REVIEW OF ADMINISTRATIVE DECISION

Plaintiff PARTNERS IN CARE, INC. (the "Hospice"), by and through its undersigned counsel, files this Complaint against Defendant XAVIER BECERRA, in his official capacity as the Secretary of the United States Department of Health and Human Services (the "Secretary"), seeking judicial review of the decision rendered by the Medicare Appeals Council ("Council") in Office of Medicare Hearings and Appeals ("OMHA") case number 3-11498188853 (Council docket number M-24-506).

PARTIES, JURISDICTION, AND VENUE

1. The Hospice is an Oregon non-profit corporation with its principal place of business located at 2075 NE Wyatt Court, Bend, Oregon 97701.

2. The Hospice is a not-for-profit, tax-exempt organization as described in Section 501(c)(3) of the Internal Revenue Code of 1986. *See* 26 U.S.C. §§ 501(a), (c)(3).

3. At all times relevant hereto, the Hospice was a Medicare-certified company offering hospice services in Oregon.

4. Defendant, Xavier Becerra, is the Secretary of the United States Department of Health and Human Services ("HHS") and the proper defendant in this action pursuant to 42 C.F.R. § 405.1136(d)(1).

5. This action arises under the United States Constitution, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. ("Medicare Act"), and the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (the "APA").

6. Prior to filing this Complaint, the Hospice filed appeals and received determinations as to all issues presented below.

7. On September 13, 2023, an administrative law judge ("ALJ") issued a partially favorable decision in this matter. Following a referral issued November 14, 2023, by the Administrative Qualified Independent Contractor ("AdQIC"), Q^2Administrators, the Council decided on its own motion to review the ALJ's decision. *See* 42 C.F.R. § 405.1110. The Hospice filed Written Exceptions to the AdQIC's referral by submitting written comments to the Council on December 4, 2023, as permitted by 42 C.F.R. § 405.1110(b)(2). The Council issued a decision on February 9, 2024. The Council's decision is final and binding on all parties unless, in relevant part, a federal district court modifies the Council's decision. *See* 42 C.F.R. § 405.1130. Thus, the

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Council's decision is the final administrative decision and is appealable to this Court under 42 U.S.C. § 1395ff(b), 42 C.F.R. § 405.1130, and 42 C.F.R. § 405.1136.

8. Therefore, because the Hospice has exhausted all administrative appeals and, thus, has no administrative remedy available to it, this Court is the proper forum to hear this Complaint.

9. As mandated by 42 C.F.R. § 405.1130, this action has been commenced within 60 days of receipt of the Council's decision dated February 9, 2024.

10. Jurisdiction is proper pursuant to 28 U.S.C. § 1331, which vests federal district courts with "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States," and 42 U.S.C. § 1395ff(b), which authorizes judicial review of the Council's decision.

11. Venue is proper pursuant to 42 U.S.C. § 1395ff(b) and 42 C.F.R. § 405.1136(b)(1), as the Hospice's principal place of business is located in this judicial district. Pursuant to LR 3, divisional venue lies in the Eugene Division because a substantial part of the events or omissions giving rise to the claim occurred in Deschutes County, Oregon.

12. The amount in controversy exceeds the threshold amount of $1,840.00 for judicial review set forth in 88 Federal Register 67297 (effective Jan. 1, 2024).

LEGAL FRAMEWORK: PROCEDURAL DUE PROCESS

13. The Fifth and Fourteenth Amendments of the U.S. Constitution guarantee rights to procedural due process. *See* U.S. Const. amend. V; U.S. Const. amend. XIV, § 1.

14. Procedural due process constrains "governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment." *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976).

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15. To demonstrate violation of procedural due process rights, a plaintiff must show that they had "(1) a protectable liberty or property interest…; and (2) a denial of adequate procedural protections." *Foss v. Nat'l Marine Fisheries Serv.*, 161 F.3d 584, 588 (9th Cir. 1998) (citing *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 569-71 (1972); *Mathews*, 424 U.S. at 335).

16. To have a constitutionally protected property interest in a benefit, a person clearly must have "a legitimate claim of entitlement to it." *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972).

17. To determine whether the procedures at issue were constitutionally adequate, courts consider: (1) the private interest affected, (2) the government's interest, and (3) the risk of erroneous deprivation of the private interest under the procedures used. *Mathews*, 424 U.S. at 335.

18. Hospices are statutorily entitled to be paid for services provided to Medicare beneficiaries that meet Medicare program requirements. *See* 42 U.S.C. § 1395f.

19. The Health Care Financing Administration (the predecessor to the Centers for Medicare and Medicaid Services ("CMS")) has indicated that when challenging the use of statistical sampling to project overpayments, providers can vindicate their rights to procedural due process only if they have a "full opportunity to demonstrate that the overpayment determination is wrong." Health Care Fin. Admin., Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers, Ruling No. 86-1 (Feb. 20, 1986).

LEGAL FRAMEWORK: THE MEDICARE HOSPICE BENEFIT

20. The Medicare Hospice Benefit is a benefit under Medicare Part A, a 100% federally subsidized health insurance program. It is administered by CMS on behalf of HHS. The Medicare Hospice Benefit pays a predetermined fee, based on the level of

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care provided by the hospice provider, for each day an eligible individual receives hospice care.

21. Through the Medicare Hospice Benefit, Medicare covers reasonable and necessary hospice services provided to eligible individuals. Services available under the Medicare Hospice Benefit are "comprehensive" and include (a) nursing care and services provided by or under the supervision of a registered nurse, (b) medical social services provided by a qualified social worker under the direction of a physician, (c) physician services, (d) counseling services, including bereavement, dietary, and spiritual counseling, (e) short-term inpatient care, (f) medical supplies, including drugs and biologicals, (g) home health aide / homemaker services, and (h) physical, respiratory, occupational, and speech therapy services. 42 C.F.R. § 418.202; *see also* 42 C.F.R. § 418.3; 42 U.S.C. § 1395x(dd).

22. CMS contracts with Medicare Administrative Contractors ("MACs"), which are private companies that process and pay Medicare claims on behalf of CMS. Other CMS divisions or contractors, such as the CMS Center for Program Integrity ("CPI"), Zone Program Integrity Contractors ("ZPICs"), and Uniform Program Integrity Contractors ("UPICs") (which succeeded and replaced the ZPICs), were and are authorized by CMS to audit claims for payment presented to Medicare by health care providers relating to services they provided to Medicare beneficiaries. These audits were and are performed on a post-payment basis to ensure that the claims complied with Medicare coverage and documentation requirements at the time they were submitted for reimbursement.

23. A Medicare contractor may, on its own motion, reopen and change its initial determination within four years after the date of the initial determination, if it has good cause to do so. 42 C.F.R. § 405.980(b)(2).

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24. In addition, HHS's Office of Inspector General ("OIG") audits health care providers that participate in Medicare pursuant to its authority to "conduct and supervise audits and investigations relating to the programs and operations" of HHS, including compliance with Medicare requirements. 5 U.S.C. § 402(b)(1).

25. However, as the OIG itself has acknowledged in this very case, "OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures." OIG, *Medicare Hospice Provider Compliance Audit: Partners In Care, Inc.* 7 n.28 (July 2021). *See also* 42 U.S.C. § 1395kk-1(a)(4)(A) (describing determination of the payment amount as a function of MACs).

26. If a CMS division, the OIG, or a CMS contractor audits and denies a claim, the affected provider may avail itself of an administrative appeals process to contest the claim denial(s). This appeals process consists of five stages: (1) redetermination, (2) reconsideration, (3) a hearing before an ALJ, (4) review by the Council, and (5) judicial review by a federal district court.

27. Requests for redetermination are processed by MACs. Requests for reconsideration are handled by separate contractors known as Qualified Independent Contractors ("QICs"). Hearing requests are adjudicated by ALJs in OMHA.

28. AdQICs review ALJ decisions. If the AdQIC believes an ALJ decision contains a material error of law, the AdQIC may refer the decision to the Council, which is a component of the HHS Departmental Appeals Board. *See* 42 C.F.R. § 405.1110(b). Parties to the ALJ decision may file exceptions to the referral by submitting written comments to the Council. *See* 42 C.F.R. § 405.1110(b)(2). The Council may then decide to review the case "on its own motion" and issue a decision. *See* 42 C.F.R. § 405.1110(a).

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29. However, when the Council reviews an ALJ's decision based on a referral from CMS or a CMS contractor, the Council must "limit its consideration of the ALJ's…action to those exceptions raised by CMS." 42 C.F.R. § 405.1110(c).

LEGAL FRAMEWORK: STATISTICAL SAMPLING AND EXTRAPOLATION

30. The "purpose" of Medicare program integrity audits is "identifying underpayments and overpayments and recouping overpayments," according to Section 1893(h)(1) of the Act, codified at 42 U.S.C. § 1395ddd(h)(1). *See also* 42 C.F.R. § 455.504 (defining the Medicare recovery audit contractor program as a program "to identify underpayments and overpayments and recoup overpayments"). An underpayment is defined as including "[n]onpayment, where payment was due but was not made." 20 C.F.R. § 416.536.

31. CMS sets forth instructions on performing statistical sampling and extrapolation in the Medicare Program Integrity Manual ("MPIM"), CMS Pub. No. 100-08. The purpose of these instructions is "to ensure that a probability sample drawn from the sampling frame of the target population yields a valid estimate of an overpayment in the target population." MPIM § 8.4.1.1.

32. ALJs are bound by "[a]ll laws and regulations pertaining to the Medicare and Medicaid programs," according to 42 C.F.R. § 405.1063(a). ALJs are not bound by "CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a).

33. However, the MPIM's statistical sampling and extrapolation guidelines are entitled only to *Skidmore* deference. *Rio Home Care, LLC v. Azar*, No. 7:17-CV-116, 2019 WL 1411805, at *26 (S.D. Tex. Mar. 11, 2019). In addition, because the MPIM has not been promulgated as a regulation by HHS, it cannot "establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services, or

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the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" through the Medicare program. 42 U.S.C. § 1395hh(a)(2).

34. Further, the MPIM itself intends auditors to base their statistical sampling and extrapolation methodology on generally accepted statistical principles as well as the MPIM. *See* MPIM § 8.4.1.5 ("The sampling methodology used in estimations of overpayments must be reviewed and approved by a statistician or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically appropriate sample is drawn, and that appropriate methods for estimating the overpayments are followed.").

35. The auditor begins the sampling process by drawing from the data set the universe of claims, which "will consist of all fully and partially paid claims submitted by the provider/supplier for the period under review." MPIM § 8.4.3.2.1.

36. From the universe, the auditor will next select the sampling frame—a list of "all the possible sampling units from which the sample is selected." MPIM § 8.4.3.2.3.

37. The auditor then uses a sampling process to choose the sample from the sampling frame. *See* MPIM § 8.4.4.1.

38. After the sample is chosen, each claim in the sample is reviewed to determine whether the claim was paid appropriately, underpaid, or overpaid. *See* MPIM § 8.4.6.3 (requiring auditors to document "the amount of all overpayments and underpayments and how they were determined."). These results are used to calculate an error rate.

39. If extrapolation is used, the error rate is extrapolated across the universe to estimate total overpayment amount. *See* MPIM § 8.2.1.1 ("A projected overpayment is the numeric overpayment obtained by projecting an overpayment from statistical sampling for overpayment estimation to all similar claims in the universe under review.").

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40. However, Section 1893(f)(3) of the Act, codified at 42 U.S.C. § 1395ddd(f)(3), prohibits Medicare auditors from using extrapolation unless HHS has determined there is a "sustained or high level of payment error" or failure of educational efforts to correct such errors. Accordingly, MPIM § 8.4.1.2 emphasizes that Section 1893(f)(3) "mandates that *before* using extrapolation…to determine overpayment amounts…, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error" (emphasis added).

41. Under MPIM § 8.4.1.4, means of determining a sustained or high level of payment error include:

a. "high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review)"

b. "provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices)"

c. "CMS approval provided in connection to a payment suspension"

d. "information from law enforcement investigations"

e. "allegations of wrongdoing by current or former employees of a provider/supplier"

f. "audits or evaluations conducted by the OIG"

42. Under Section 1893(f)(3) of the Act and MPIM § 8.4.1.2, the determination of a high level of payment error is not subject to review. However, Section 1893(f)(3)'s prohibition against review violates providers' due process rights. In another recent case, another provider challenged the use of extrapolation by arguing that the Defendant's use of extrapolation without giving providers a meaningful process to challenge it

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violates providers' due process rights. *See* Complaint at 11–16, *Merit Leasing Co. v. Becerra*, No. 1:23-CV-859 (N.D. Ohio Apr. 24, 2023). The Defendant settled with the provider by agreeing to pay 88% of the amount owing to the extrapolation. *See id.* at 3–4 (stating that after appeals, the alleged overpayment for claims in the sample was $37,304.69 and the total overpayment demand following extrapolation was $417,275.00); Stipulation of Settlement at 2, *Merit Leasing Co. v. Becerra*, No. 1:23-CV-859 (N.D. Ohio Mar. 7, 2024) (stating that the Defendant agreed to settle by paying $335,000.00).

43. Even if Section 1893(f)(3) did not violate providers' due process rights, neither Section 1893(f)(3) nor MPIM § 8.4.1.2 indicates that the question of *whether the auditor ever made such a determination* before deciding to extrapolate is likewise unreviewable.

44. Further, under both generally accepted statistical principles and the MPIM, statistical samplings are invalid if they do not result in a probability sample. *See* MPIM § 8.4.2. A probability sample is one in which each sample, and each unit of each possible sample, has "a known probability of selection." *Id.*

45. Relatedly, auditors must "document all steps taken in the random selection process exactly as done to ensure that the necessary information is available for anyone attempting to replicate the sample selection," MPIM § 8.4.4.2, and "maintain complete documentation of the sampling methodology that was followed," MPIM § 8.4.4.4. This includes documenting the universe definition and elements, period covered, sampling unit definitions and identifiers, dates of service, source, sampling frame, and the random numbers used and how they were selected. MPIM § 8.4.4.4.1. This same section requires that sufficient documentation be kept so that the sampling frame can be re-created if the methodology is challenged. *Id.*

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46. The Medicare Appeals Council has reversed extrapolations because the auditor failed to maintain documentation necessary to replicate the sampling process, emphasizing its importance to providers' due process rights. *See*, e.g., *Glob. Home Care, Inc.*, M-11-116, at 4 (Medicare Appeals Council Jan. 11, 2011) ("The sampling frame cannot be recreated from the documentation present. Without this basic documentation, a provider does not have the information and data necessary to mount a due process challenge to the statistical validity of the sample, as is its right under CMS Ruling 86-1."); *Podiatric Med. Assocs.*, M-10-230, at 20 (Medicare Appeals Council June 22, 2010) ("It is well-established that due process affords an appellant provider the right to examine audit results in order to mount a proper challenge in the appeals process….Absent supporting evidence, the appellant is deprived of its ability to review the extrapolation in question.").

47. When creating the sampling frame, auditors must include potential underpayments. In accordance with the statutory requirement to identify both underpayments and overpayments, as set forth in Section 1893(h)(1) of the Act, many sections of the MPIM require auditors to net underpayments against overpayments when estimating the total overpayment amount. *See*, *e.g.*, MPIM § 8.4.5.2 ("Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall be used in calculating the estimated overpayment."); MPIM § 8.4.1.3 (stating that one of the eight "major steps in conducting statistical sampling" is "[e]xamining each of the sampling units and determining if there was an overpayment *or an underpayment*" (emphasis added)). For Corporate Integrity Agreements, the OIG itself has recently begun to explicitly require the inclusion of underpayments to calculate the overpayment demand. *See* OIG, HHS, Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and CHC-

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FLA, LLC, App'x B, at 1 (Sept. 26, 2022), https://www.oig.hhs.gov/fraud/cia/agreements/CHC-FLA_Inc_09262022.pdf.

48. Auditors must also take care in determining the sample size, which has "a direct bearing on the precision of the estimated overpayment." MPIM § 8.4.4.3. Accordingly, the MPIM instructs auditors not to choose a sample size arbitrarily but to consider multiple factors to determine the sample size. *See id.* ("It is neither possible nor desirable to specify a minimum sample size that applies to all situations.")

49. Although the MPIM does not set a threshold for an acceptable precision, at the time this audit began, the OIG itself required a precision higher than 25% for its Medicare claim reviews conducted against providers with whom it has Corporate Integrity Agreements, unless the OIG used RAT-STATS or equivalent statistical software to choose the sample size. In addition, another federal district court case invalidated a contractor sampling and extrapolation because the precision of 32.5% was unacceptably high (a higher percentage reflecting a worse precision). *See Central Louisiana Home Health Care, L.L.C. v. Price*, No. 1:17-CV-00346, 2018 WL 7888523, at *20 (W.D. La. Dec. 28, 2018).

STATEMENT OF FACTS

50. The Hospice is a not-for-profit hospice that serves rural communities in Central Oregon. It is the primary independent, non-hospital-based hospice in the area, with only one other hospice in the area whose patient census is just 10% of that of the Hospice's. The Hospice has continuously served terminally ill individuals and their families in the state since its founding in 1979. Currently, the Hospice provides hospice services, including Medicare-covered hospice services, to Oregonians across 5 counties.

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51. In a letter sent to the Hospice on May 30, 2018, the OIG, on behalf of CMS, informed the Hospice of its intention to audit sampled claims related to services provided by the Hospice between January 1, 2016, and December 31, 2017.

52. The OIG subsequently requested medical and billing records from the Hospice pertaining to a "random sample" of 100 claims (for which the Hospice had been paid $478,696 by CMS) out of 5,779 claims (for which the Hospice had been paid $27,319,955 by CMS) the Hospice submitted to CMS for payment for services provided from January 1, 2016, through December 31, 2017. The Hospice promptly complied with this request and provided the OIG with thousands of pages of responsive records for review.

53. In a draft report dated November 2020 ("Draft Report"), the OIG informed the Hospice that for 47 of the 100 claims reviewed, the clinical record did not support that the patients were terminally ill (43 claims) or did not support the level of care provided (4 claims). Based on an extrapolation of the sample results, the OIG estimated that the Hospice received approximately $11.2 million in unallowable Medicare reimbursement for hospice services. The Draft Report further recommended that the Hospice refund to Medicare the portion of the estimated $11,278,891 attributable to the claims that did not comply with Medicare requirements and fell within the four-year reopening period.

54. The Hospice responded to the Draft Report in a letter dated January 22, 2021. The response refuted the findings and recommendations set forth in the OIG's Draft Report by, among other things, providing rebuttal statements supporting clinical eligibility for 45 out of the 47 allegedly non-compliant claims. The response also included a report (dated January 21, 2021) prepared by statistical expert R. Mitchell Cox, Ph.D., identifying numerous flaws in the OIG's sampling and extrapolation methodology.

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55. In its final report dated July 2021 ("Final Report"), the OIG maintained the validity of its findings, recommendations, and sampling and extrapolation methodology.

56. By the time the OIG issued its Final Report, several claims fell outside four-year the reopening window. The Hospice's MAC, National Government Services, Inc. ("NGS"), recalculated the OIG's extrapolation by first setting all claims falling outside the reopening window to zero dollars. The Hospice then received a demand letter from NGS, dated August 16, 2021, asserting that the Hospice must refund to Medicare an overpayment amount of $2,286,313.00.

57. The Hospice initiated an appeal of the OIG's Final Report and NGS's demand letter through the Medicare administrative appeals process. On December 9, 2021, the Hospice filed a request for redetermination with NGS, seeking review of the 13 denied claims within the four-year reopening period. The redetermination request included rebuttal statements prepared by board-certified hospice physicians Edward Martin, MD, MPH, FACP, FAAHPM, and John Mulder, MD, MS, HMDC, FAAHPM, and a statistical expert report (dated December 8, 2021) revised by Dr. Cox in response to NGS's demand letter.

58. In its redetermination decision dated February 4, 2022, NGS upheld the denial of all 13 claims at issue.

59. On July 28, 2022, the Hospice filed a request for reconsideration. The reconsideration request included updated physician clinical summaries prepared by either Dr. Martin or Dr. Martin, as well as a revised statistical expert report (dated December 8, 2022) and reply to NGS's redetermination decision (dated July 25, 2022) by Dr. Cox.

60. In its reconsideration decision dated September 27, 2022, C2C decided one claim favorably and another claim partially favorably. C2C upheld the denial of the remaining 11 claims.

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61. On November 21, 2022, the Hospice filed a request for hearing before an ALJ, seeking review of all 12 remaining denied claims. On January 10, 2023, the Hospice received notice that the appeal would be adjudicated by ALJ Eli Bruch.

62. In advance of the scheduled ALJ hearing, on June 14, 2023, the Hospice submitted a position statement to ALJ Bruch. The position statement summarized certain relevant legal, medical, and statistical authorities that supported the propriety of the claims at issue and demonstrated the invalidity of the OIG's sampling methodology and extrapolation.

63. The position statement also introduced the Hospice's expert witnesses, including clinical experts Dr. Martin and Dr. Mulder and statistical expert Dr. Cox. In addition, the position statement included the written testimony of the Hospice's medical director, Lisa Lewis, MD, HMDC, and associate medical director, Jennifer Blechman, MD, HMDC, FAAHPM, confirming that the medical records supported the original eligibility and level-of-care determinations they or the other hospice physicians made with respect to the claims at issue. Also included was a statistical expert reply to C2C's reconsideration decision (dated April 4, 2023) by Dr. Cox.

64. The hearing took place before ALJ Bruch on June 21, 2023. No party other than the Hospice appeared at the hearing.

65. At the hearing, Drs. Martin, Mulder, Lewis, and Blechman provided medical opinion testimony on behalf of the Hospice and were the *only* expert physician witnesses to testify. Dr. Cox, the only expert statistician to testify, explained how, based on his thorough analysis of the statistical sampling and extrapolation materials received from the OIG and NGS, the sampling and extrapolation were statistically invalid.

66. Based on the unrefuted expert medical opinion testimony supporting the propriety of the claims at issue, ALJ Bruch issued a decision on September 13, 2023,

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that upheld the denial of only 4 of the appealed claims, issuing fully favorable decisions regarding all the other appealed claims.

67. ALJ Bruch also found that the statistical sampling and extrapolation methodology was invalid, citing three reasons: (1) the inclusion of claims from before the four-year reopening period in the universe of claims, (2) the OIG's insufficient prospective documentation of the planned sampling process, and (3) the exclusion from the sampling frame of claims paid less than $1,000 (but more than $0).

68. ALJ Bruch opined that each of these three failures was sufficient by itself to invalidate the statistical sampling and extrapolation. *See* ALJ Decision at 21 ("The combined effect of these failures, *and the individual failures themselves*, rises to a level beyond a mere failure to follow steps, but demonstrably and irreparably affects the validity of the statistical sample as drawn and conducted. *See MPIM*, ch. 8, § 8.4.1.1.") (emphasis added).

69. ALJ Bruch also agreed in principle with the Hospice's argument that the overpayment estimate should be offset by amounts otherwise payable under Medicare Part B or Part D. *See* ALJ Decision at 21 ("Appellant makes compelling arguments regarding the structure [of] Medicare regulations, specifically surrounding hospice care and statistical sampling.") However, ALJ Bruch stated that the administrative appeals process was not the proper forum because it is "not one of general jurisdiction." *Id.*

70. As a result of ALJ Bruch's decision, the payment error rate now stands at only 4.6%, far below the 50% threshold required for extrapolation.

71. On November 14, 2023, Q^2Administrators referred the ALJ's decision to the Council for review on CMS's own motion. In the referral, Q^2Administrators raised exceptions related only to two issues: the ALJ's determinations that (1) the OIG's insufficient sampling plan and (2) the universe's inclusion of claims outside the four-year reopening period invalidated the sampling and extrapolation.

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72. On December 4, 2023, the Hospice submitted to the Council Written Exceptions to Q^{2}Administrators' referral, requesting that the Council refrain from reviewing the case on its own motion. The Hospice's Written Exceptions also explained why ALJ Bruch's favorable conclusions regarding the statistical sampling and extrapolation were correct and why his unfavorable conclusions regarding the same were incorrect. The Hospice's Written Exceptions are attached hereto as Exhibit A and incorporated herein by reference.

73. On February 9, 2024, the Council issued a Notice of Own Motion Review and Decision. The Council's decision found that the statistical sampling and extrapolation methodology were valid. To reach that conclusion, the Council rejected not only the two issues that Q^{2}Administrators raised in its referral but also all the other reasons identified by ALJ Bruch for invalidating the statistical sampling and extrapolation methodology and the arguments the Hospice raised in the position statement it submitted to ALJ Bruch and in its Written Exceptions.

74. The Hospice has thus exhausted its administrative remedies, and this case is eligible for judicial review.

75. This Complaint is timely filed within 60 calendar days after the Hospice received notice of the Council's decision. *See* 42 C.F.R. § 405.1130.

FIRST CLAIM FOR RELIEF

VIOLATION OF THE SOCIAL SECURITY ACT

The Use of Extrapolation Violated Section 1893(f)(3).

76. The Hospice hereby incorporates by reference paragraphs 1 through 75 herein.

77. The Defendant's use of extrapolation violated Section 1893(f)(3) of the Act. The Defendant did not make a determination that there was a "sustained or high level of payment error" before deciding to extrapolate. In fact, the OIG tacitly admitted

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as much. In its final report, the OIG stated, "the MPIM requirement that a determination of a sustained or high level of payment errors must be made before extrapolation applies only to Medicare contractors—not OIG." OIG, *Medicare Hospice Provider Compliance Audit: Partners In Care, Inc.* 13 (July 2021).

78. NGS also tacitly admitted that it never made the determination of a sustained or high level of payment error. In correspondence sent to CMS on March 26, 2024, counsel for the Hospice cited Section 1893(f)(3) and wrote, "it appears nobody at CMS or the MAC made the determination of a sustained or high level of payment error. If that is incorrect, let us know." NGS's response, dated March 27, 2024, stated, "The OIG used the extrapolation to determine the overpayment amounts. This section [Section 1893(f)(3)] would not be applicable to NGS." *See* Exhibit B. Thus, by their own admission, neither the OIG nor NGS ever made a determination of a sustained or high level of payment error.

79. Further, NGS's response shows that it misinterprets the OIG's audit as a final determination of overpayment, which the OIG explicitly stated it was not. CMS is responsible for ensuring that NGS performs its responsibilities in compliance with the law.

80. In addition, although the MPIM states that "audits or evaluations conducted by the OIG" are one possible criterion that may be used to determine a sustained or high level of payment error," this blatantly conflicts with the statute. The simple fact that the OIG is performing a review cannot establish that a payment error is high.

81. The payment error rate in this audit is 4.6%, well below Defendant's 50% threshold for extrapolation.

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82. Because the use of extrapolation violated Section 1893(f)(3) of the Act, this Court should declare that the extrapolation was statutorily unauthorized and should enjoin the Defendant from using extrapolation in this case.

SECOND CLAIM FOR RELIEF

VIOLATION OF THE MEDICARE OVERPAYMENT AND PROCEDURAL REGULATIONS

The Council Overstepped Its Regulatory Authority in Deciding a Non-Referred Issue

83. The Hospice hereby incorporates by reference paragraphs 1 through 82 herein.

84. ALJ Bruch gave three independent reasons for finding that the statistical sampling and extrapolation was invalid: (1) the inclusion of claims from before the four-year reopening period in the universe of claims, (2) the OIG's insufficient prospective documentation of the planned sampling process, and (3) the exclusion from the sampling frame of claims paid less than $1,000 (but more than $0).

85. In its referral, Q^2Administrators raised exceptions only regarding the first two issues. It identified no error of law regarding ALJ Bruch's decision that the exclusion from the sampling frame of claims paid less than $1,000 invalidated the sampling and extrapolation.

86. In its decision, however, the Council attempted to reverse ALJ Bruch's decision regarding all three issues.

87. In purporting to reverse ALJ Bruch's decision that the exclusion from the sampling frame of claims paid less than $1,000—which Q^2Administrators did not raise in its referral—the Council violated the regulatory command that the Council "limit its consideration of the ALJ's…action to those exceptions raised by CMS."

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88. As a result, ALJ Bruch's conclusion that the exclusion of claims paid less than $1,000 invalidates the sampling and extrapolation is the Defendant's final decision on the matter.

89. Because the Council overstepped its regulatory authority in deciding a non-referred issue, this Court should reverse the Council's decision that the sampling and extrapolation were valid.

The Inclusion of Claims Outside the Reopening Period Violated the Regulations.

90. The Hospice hereby incorporates by reference paragraphs 1 through 89 herein.

91. The Medicare overpayment and procedural regulations limit a CMS contractor's authority to reopen claims more than four years after the initial determination. *See* 42 C.F.R. § 405.980(b)(2).

92. By the time the OIG issued its Final Report, several claims fell outside the four-year the reopening window. Although NGS recalculated the OIG's extrapolation by first setting all claims falling outside the reopening window to zero dollars, the result was that the Defendant applied statistical sampling and extrapolation to a universe that included claims outside the regulatory reopening period. Thus, the Defendant demanded repayment for claims outside the reopening period, violating the Medicare overpayment and procedural regulations.

93. Because the Defendant's application of statistical sampling and extrapolation to a universe that included claims outside the regulatory reopening period violated Medicare overpayment and procedural regulations, this Court should reverse the Council's decision that the sampling and extrapolation were valid.

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THIRD CLAIM FOR RELIEF

VIOLATION OF THE MEDICARE ACT AND ADMINISTRATIVE PROCEDURE ACT

The Council's Decision Is Arbitrary and Capricious

94. The Hospice hereby incorporates by reference paragraphs 1 through 93 herein.

95. Under the Administrative Procedure Act, courts must set aside agency actions and decisions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

96. The Council's decision is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in several respects. These include, without limitation:

a. The Council's decision that the inclusion of claims paid less than $1,000 in the sampling frame does not invalidate the universe blatantly and unreasonably contradicts Medicare program integrity statues and regulations and the Defendant's own guidance, all of which require auditors to net underpayments against overpayments when estimating the total overpayment amount.

b. The Council concluded that the OIG's documentation of its sampling process was sufficient, even though there was no evidence that the OIG chose all the parameters needed to produce the sample *before* beginning the sampling process. The Council's decision perversely enables auditors to run multiple samples and choose the one likely to generate the highest overpayment estimate.

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c. The Council's decision that the application of statistical sampling and extrapolation to a universe that included claims outside the reopening period renders the regulatory window meaningless.

97. Because the Council's decision is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, this Court should reverse the Council's decision that the sampling and extrapolation were valid and should enjoin the Defendant from using extrapolation in this case.

The Council Erred in Upholding the ALJ's Unfavorable Determinations

98. The Hospice hereby incorporates by reference paragraphs 1 through 97 herein.

99. ALJ Bruch's unfavorable decisions regarding the statistical sampling and extrapolation were not supported by substantial evidence in that they:

a. Failed to address whether the OIG ever made a determination of a high level of payment error;

b. Determined that the high precision, inclusion of dependent claims, and exclusion of zero-paid claims did not invalidate the statistical sampling and extrapolation; and

c. Failed to determine that the overpayment estimate should be offset by amounts otherwise payable under Medicare Part B or Part D.

100. This Court should reverse the Council's decisions upholding the ALJ's unfavorable clinical and statistical determinations.

FOURTH CLAIM FOR RELIEF

VIOLATION OF THE MEDICARE PROGRAM INTEGRITY MANUAL

101. The Hospice hereby incorporates by reference paragraphs 1 through 100 herein.

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102. The MPIM intends auditors to base their statistical sampling and extrapolation methodology on generally accepted statistical principles as well as the MPIM.

103. The Defendant violated generally accepted statistical principles and the MPIM in multiple ways, including without limitation:

a. Neither the OIG nor CMS ever made a determination of a sustained or high level of payment error before the audit began. Rather, the Defendant decided to extrapolate *before* making a determination of a sustained or high level of payment error, violating MPIM § 8.4.1.2 (as well as Section 1893(f)(3) of the Act). In addition, the Defendant may not extrapolate in the same review that supposedly determines a high level of error. As MPIM § 8.4.1.4 states, extrapolation cannot be used until there has been a "*previous*… review" showing a high error rate (emphasis added).

b. The statistical sampling was invalid because it did not result in a probability sample. The OIG failed to produce any evidence showing that it decided how to order the claims within the sampling frame or chose the random number seed *before* beginning the sampling process. As a result, neither each sample nor each unit of each sample had "a known probability of selection" when sampling began, as required by generally accepted statistical principles and MPIM § 8.4.2. Because it did not result in a probability sample, the sampling was invalid.

c. By failing to produce evidence that all the parameters needed to produce the sample were chosen before sampling began, auditors can run multiple samples and choose the one likely to generate the

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highest overpayment estimate. In such circumstances, providers would be highly unlikely to be able to detect and prove such activity.

d. According to the OIG's sampling plan, the OIG removed all claims paid less than $1,000, including claims paid zero dollars, from the sampling frame. Statistically, exclusion of claims paid less than $1,000 served only to artificially inflate the overpayment estimate. This also violated the many sections of the MPIM that require auditors to net underpayments against overpayments when estimating the total overpayment amount (as well as the statutory command to identify underpayments as well as overpayments).

e. Instead of using statistical software or considering multiple factors to determine an appropriate sample size, the OIG arbitrarily chose a sample size of 100—the same sample size that the OIG has used in at least seven other audits reviewed by Dr. Cox. Choosing a sample size without undertaking any analysis to determine whether the sample size is adequate violates generally accepted statistical principles. It also violates MPIM § 8.4.4.3's specific directive not to "specify a minimum sample size that applies to all situations."

f. The OIG's selection of an inadequate sample size resulted in an unacceptably high (poor) precision of 45.76% even before the ALJ's decision. This means that, in the event the Hospice is asked to reimburse more than it has been overpaid, it will be asked to over-reimburse more than four and a half times the amount it would have been asked to reimburse had the precision been a more standard 10%. The precision has likely worsened even further since the ALJ's decision.

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g. For any claim in its sample belonging to a patient with dementia, the OIG reviewed not only that claim but also claims submitted for the same patient during the previous 12-month period. This prevented the sampling units from being independent, which is required for simple random sampling, the type of sampling the OIG used in this case.

104. Because of the Defendant's multiple, serious violations of generally accepted statistical principles and the MPIM, the Council's decision should be reversed.

FIFTH CLAIM FOR RELIEF

VIOLATION OF THE HOSPICE'S DUE PROCESS RIGHTS UNDER THE U.S. CONSTITUTION

The Prohibition Against Review Violates the Hospice's Due Process Rights

105. The Hospice hereby incorporates by reference paragraphs 1 through 104 herein.

106. The Hospice has a protected property interest because it is entitled to payments for services that met the federal hospice Conditions of Payment.

107. Both CMS (through Ruling 86-1) and the Council have acknowledged that statistical sampling and extrapolation implicate providers' due process rights.

108. The prohibition against administrative and judicial review of HHS's determination that there has been a sustained or high level of payment error, as set forth in Section 1893(f)(3) of the Act and MPIM § 8.4.1.2, deprives the Hospice of an appropriate level of process. Extrapolation vastly multiplies overpayment estimates—as well as any unresolved errors the auditor has made. Thus, the Hospice faces a tremendous risk that it will be erroneously deprived of funds to which it was entitled if the sole determination that authorizes the extrapolation is unreviewable.

109. Therefore, this statutory and agency prohibition against review violates the Hospice's due process rights under the U.S. Constitution.

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110. Because the prohibition against review violates providers' due process rights, this Court should declare that the prohibition against review of the Defendant's determination of a high level of payment error, which is set forth in Section 1893(f)(3) and MPIM § 8.4.1.2, violates the due process clauses of the Fifth and Fourteenth Amendments of the U.S. Constitution. Moreover, this Court should enjoin the Defendant from using extrapolation in this case.

The Decision to Use Extrapolation Violated the Hospice's Due Process Rights

111. The Hospice hereby incorporates by reference paragraphs 1 through 110 herein.

112. The Defendant's decision to use extrapolation violated the Hospice's due process rights because the Defendant decided to use extrapolation *before* making a determination of a sustained or high level of payment error. In fact, the Defendant never made such a determination. This decision deprived the Hospice of an appropriate level of process because it permitted the Defendant to decide to extrapolate for any reason or for no reason at all. Thus, the Hospice is highly likely to be erroneously deprived of funds to which it was entitled.

113. Because the Defendant decided to extrapolate without making a determination of a sustained or high level of payment error, this Court should declare that the Defendant violated the Hospice's due process rights and should enjoin the Defendant from using extrapolation in this case.

The Council's Decision on a Non-Referred Issue Violated the Hospice's Due Process Rights

114. The Hospice hereby incorporates by reference paragraphs 1 through 113 herein.

115. The regulatory command that the Council "limit its consideration of the ALJ's…action to those exceptions raised by CMS" in its referral serves as notice to

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providers such as the Hospice that the Council will not decide issues that the ALJ decided that CMS does not raise in the referral.

116. By instead deciding an issue not raised in the referral, the Council deprived the Hospice of an adequate level of process by rendering meaningless a key administrative procedure requirement. It also disrupted the Hospice's justified expectations regarding the resolution of that issue and the validity of the statistical sampling and extrapolation. As a result, the Hospice was at great risk of being erroneously deprived of funds to which it was entitled.

117. Because the Council issued a decision on a non-referred issue, this Court should declare that the Defendant violated the Hospice's due process rights and should reverse the Council's decision that the sampling and extrapolation were valid.

The Exclusion of Claims Paid Less than $1,000 Violated the Hospice's Due Process Rights

118. The Hospice hereby incorporates by reference paragraphs 1 through 117 herein.

119. The Defendant's exclusion of all claims paid less than $1,000 violated the Hospice's due process rights. Excluding such claims serves no purpose other than to artificially inflate the overpayment estimate, placing the Hospice at tremendous risk of being erroneously deprived of funds to which it was entitled.

120. Because the Defendant wrongfully excluded claims paid less than $1,000 from the sampling frame, this Court should declare that the Defendant violated the Hospice's due process rights and reverse the Council's decision that the sampling and extrapolation were valid.

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Including Claims Outside the Reopening Period Violated the Hospice's Due Process Rights

121. The Hospice hereby incorporates by reference paragraphs 1 through 120 herein.

122. The regulatory limit on a CMS contractor's authority to reopen claims more than four years after the initial determination serves as notice to providers such as the Hospice that the Defendant will not disturb old claims.

123. However, by applying statistical sampling and extrapolation to a universe that included claims outside the regulatory reopening period and demanding payment for such claims, the Defendant deprived the Hospice of an adequate level of process and disrupted the Hospice's justified expectations regarding how long they are liable for old claims. Administrative delay is no excuse: If auditors have trouble conducting audits within four years, they can take many steps to address the problem (*e.g.*, choose shorter audit periods, perform fewer audits) that do not violate providers' due process rights. Under the circumstances, however, the Hospice was at great risk of being erroneously deprived of funds to which it was entitled.

124. Because the Council applied statistical sampling and extrapolation to a universe that included claims outside the regulatory reopening period and demanded payment for such claims, this Court should declare that the Defendant violated the Hospice's due process rights and should reverse the Council's decision that the sampling and extrapolation were valid.

The Multiple Fatal Statistical Errors Violated the Hospice's Due Process Rights

125. The Hospice hereby incorporates by reference paragraphs 1 through 124 herein.

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126. The Defendant's failure to adhere to generally accepted statistical principles and its own guidance, the MPIM, violated the Hospice's due process rights.

127. The Defendant decided to extrapolate without determining that there was a high level of payment error, ensured an artificially inflated overpayment by excluding claims paid less than $1,000, included claims that were not statistically independent, chose the sample size arbitrarily and without undertaking any analysis, used a statistically invalid sample (*i.e.*, not a probability sample), and then used the results to perform the unauthorized extrapolation the Defendant had planned to use from the beginning. Under any one of these circumstances, the Hospice's risk of being erroneously deprived of funds to which it was entitled was terribly high.

128. As a result of the Defendant's many fatal failures to adhere to generally accepted statistical principles and the MPIM, this Court should declare that the Defendant violated the Hospice's due process rights and reverse the Council's decision that the sampling and extrapolation were valid.

PRAYER FOR RELIEF

WHEREFORE, the Hospice respectfully requests that this Court:

A. Reverse the Council's decision that the sampling and extrapolation were valid;

B. Declare that extrapolation was statutorily unauthorized in this case;

C. Enjoin the Defendant from using extrapolation in this case;

D. Declare that Section 1893(f)(3)'s prohibition against review of the Defendant's determination of a high level of payment error violates the due process clauses of the Fifth and Fourteenth Amendments of the U.S. Constitution;

E. Declare that the Defendant violated the Hospice's due process rights under the U.S. Constitution;

F. Find that the Council erred in upholding the ALJ's unfavorable determinations;

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G. Hold that the Defendant's position was not substantially justified;

H. Award the Hospice attorney fees under the Equal Access to Justice Act; and

I. Grant the Hospice any other legal or equitable relief that the Court may deem just and proper.

DATED this 9th day of April, 2024.

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